510k: K093183

SECTION 6

OCT 23 2009

510(k) SUMMARY
Date Prepared: August 31, 2009

1. Company Name and Address

Aspect Medical Systems, Inc.
One Upland Road
Norwood, MA 01532

Contact Person: Vikram Verma
Sr. Manager, RA/QA
Telephone (direct dial): (617) 559-7134
Fax #: (617) 559-7948

2. Device Name

Proprietary Name: BIS Quatro Sensor
Common Name: Electrode, Cutaneous Electrode

3. Classification

Cutaneous Electrodes have been classified by the Neurological Devices Panel as Class II, 84 GXY. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for cutaneous electrodes. (21 CFR 882.1320).

6. Predicate Device

Aspect Medical Systems Enhanced BIS Sensor
This 510(k), # K002734, received FDA clearance on September 14, 2000

7. Device Description

This 510(k) is being submitted for the BIS Quatro which is a minor modification to the 510(k) cleared Enhanced Sensor (K#002734). The formulation of the aqueous hydrogel is being changed.

A hazard analysis was conducted for the device. All identified hazards have been sufficiently mitigated. A summary of validation test results is included in this 510(k). All the results are acceptable.

Aspect Medical Systems has concluded that the device is substantially equivalent to the predicate device (BIS Enhanced Sensor, K#002734), and is safe and effective for its intended use.

Indications for use for Quatro Sensor:

The BIS Quatro sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.

Summary of Technological Characteristics Compared to Predicate Device

The BIS Quatro has the same intended use and fundamental scientific technology as the predicate device, Enhanced Sensor (K#002734).

Summary of Testing

The following tests/analyses have been completed for the BIS Quatro:

- Electrical
- Mechanical
- Shelf Life
- Biocompatibility
- Hazard Analysis

Results indicate the device meets its performance specifications and is safe for its intended use.

Conclusion:

Based on the above, Aspect Medical Systems believes the BIS Quatro Sensor is substantially equivalent to the predicate device, and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Aspect Medical Systems, Inc.
c/o Mr. Casey Conry
Underwriters Laboratories, Inc.
1285 Walt Whitman Rd
Melville, NY 11747

OCT 23 2009

Re: K093183
Trade/Device Name: BIS Quatro Sensor
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: II
Product Code: GXY
Dated: October 8, 2009
Received: October 9, 2009

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093183

Indications for Use

510(k) Number (if known) K093183

Device Name BIS Quatro Sensor

Indications for Use

The BIS Quatro sensor is applied directly to the patient's skin to enable recordings of electrophysiological (such as EEG) signals.

Prescription Use __X_____ AND/OR Over-TheCounter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K093183